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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/518,103

10/14/2005

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01/21/2010

EXAMINER

SKOWRONEK, KARLHEINZ R

ART UNIT

PAPER NUMBER

1631

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/518,103	Applicant(s) BUGRIM ET AL.	
	Examiner KARLHEINZ R. SKOWRONEK	Art Unit 1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 October 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3,5-10 and 13-25 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3,5-10 and 13-25 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>09/22/09</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Status

Claims 1, 3, 5-10, 13-25 are pending.

Claims 2, 4, and 11-12 are cancelled.

Claims 13-25 are new

Claims 1, 3, 5-10, 13-25 have been examined.

Claims 1, 3, 5-10, 13-25 are rejected.

Priority

This application was filed on 14 October 2005 under 35 USC 371 as the national stage of PCT/US03/19325, which was filed on 18 June 2003 and claims the priority of US provisional Application No. 60/389474, which was filed on 18 June 2002.

Information Disclosure Statement

The information disclosure statement (IDS) submitted on 22 September 2009 is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

Claim Rejections - 35 USC § 101

Response to Arguments

The rejection of claims 1, 3, and 5-11 as Non-Statutory under 35 USC 101 is withdrawn in view of the amendments to the claims.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

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The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The following rejection is new.

Claims 1, 3, 5-10, 13-25 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. THIS IS A NEW MATTER REJECTION.

Independent claims 1,3, and 19 are directed to articles of manufacture comprising a computer readable medium having embodied thereon a set of program instructions. A review of the specification does not provide written description for an article of manufacture configured to perform a method of reconstructing human metabolism. As indicated in applicant's arguments, filed 08 October 2009 the specification at p. 6 paragraph 2 indicates that algorithms can be developed. However, the general statement regarding the ability to develop algorithms does not provide support for the instantly claimed article of manufacture. Applicant has also indicated the specification at p. 6, paragraph 3 supports the instantly claimed article of manufacture. The specification at p. 6 paragraph 3 indicates a relational database has been created. It does not provide support for the instantly claimed article of manufacture. The specification is silent regarding with regard to written support for an article of manufacture as instantly claimed.

The claims are also amended to recite that the interactive map is of human metabolism is created exclusively from data collected regarding human metabolism. The limitation of an interactive map is of human metabolism is created exclusively from data collected regarding human metabolism is new matter. The specification however teaches at p. 5, paragraph 2,

"The process of System Reconstruction generally starts with the creation of a collection of metabolic pathways. Pathways that are human specific and in the form in which they occur in humans are included. Building such a collection is achieved through a multi-level annotation process. Starting with a collection of identified metabolic pathways from mammals and non-mammals, the pathways are divided into categories based on relevance."

The specification does not support the creation of an interactive map exclusively from human data. The claims have been amended to recite display on a computer screen. A review of the specification reveals the specification as originally filed is silent with respect the instantly claimed computer screen. Therefore, the claim lacks written description. Claims 5-10, 13-18, and 20-25 are also rejected because they depend from claim 1, 3, and 19 and thus contain the above issues due to said dependence.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following rejection is new.

Claims 1, 3, 5-10, 13-25 are rejected under 35 U.S.C. 102(b) as being anticipated by Buechler et al. (US PAT 6,074,616).

Claims 1, 3, 5-10, 13-25 are directed to an article of manufacture comprising a computer readable medium having embodied thereon a set of program instructions. The limitations following the phrase "configured to enable" are intended use limitations and do not further limit the article of manufacture.

Buechler et al. shows an article of manufacture comprising a computer readable medium having stored therein computer software (col. 22, line 5-18).

Claim Rejections - 35 USC § 103

Response to Arguments

The rejection of claim 11 is withdrawn in view of the cancellation of claim 11.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

The following rejection is necessitated by amendment of the claims.

Claims 1, 3-5, 7-10, 13, 15-20, and 22-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nakao et al. as supported by the KEGG table of contents as of February 1999(online resource, [<http://web.archive.org/web/19990203053246/www.genome.ad.jp/kegg/kegg2.html>]), in view of Karp et al. and in view of Kuffner et al. (Bioinformatics, Vol. 16, No. 9, p 825-836, 2000), in view of Ishizuka et al. (Information processing society of Japan, Vol. 91, p. 73-80, 27 September 2000) and in view of Takai-Igarashi et al. (In Silico Biology, Vol. 1, p. 129-146, 1999).

The claims are directed to a method for reconstruction of the metabolism of an organism in which data regarding the organism metabolism is collected; linked to metabolic pathways; interconnections between metabolic pathways are identified; and a map of the organism's metabolism is created.

Nakao et al. shows a method of metabolism reconstruction. Nakao et al. shows that data regarding the organism's metabolism is collected (sect 3.1). Nakao et al. shows data is linked to metabolic pathways and that inter-connections are identified to

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create a map of the organism's metabolism (figure 4). Nakao et al. shows that the metabolic reconstruction also comprises data regarding metabolism of an organism for both a reference (non-diseased) and perturbed (diseased) state (p. 95). Nakao et al. refers to reference and perturbed states, and the KEGG database actually contains data related to diseased and non-diseased states in humans (see the KEGG database table of contents from February 1999) Nakao et al. shows that pathway maps can be reconstructed for eukaryotes such as fruit fly, mouse, human, and *Saccharomyces cerevisiae*.

Nakao et al. does not show the identification of drug targets.

Karp et al. shows that drug targets can be identified through the analysis of pathway genome databases (p. 278, col. 2 to p. 279, col. 1). Karp et al. shows that that integrated genome-metabolic pathways provide a framework for improved drug discovery (abstract).

Kuffner et al. shows a method of that combines the information found on various metabolic databases to produce a differential metabolic display (DMD). The DMD of Kuffner et al. allows the comparison between disease pathways and non-disease pathways (p. 825, col. 2 –p. 825, col. 1). Kuffner et al. suggests differences can be identified from the comparison. Kuffner et al. shows that the data to generate DMD's are taken from such databases as KEGG (p. 826, col. 1). Kuffner et al. shows the type of data obtained from the databases comprises biochemical units further comprising metabolic steps (enzymes), chemical compounds (ligands, cofactors, substrates, and products), reactions, and enzymatic function (genes and proteins) (p. 826, col. 2 and

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figs1 and 5). Kuffner et al. shows an annotation table comprising fields such as sub cellular localization and intracellular compartmentalization (figure 5). Kuffner et al. suggests that DMD will be useful for target identification (abstract). Kuffner et al. shows DMD's allow the display of significant differences, to identify gaps in specific pathways and enable the interpretation of expression data by making predictions for proteins of unknown function and to propose the existence and/or absence of specific proteins or protein functions (p. 834, col. 2).

Nakao et al. does not show an interactive map is created.

Ishizuka et al. shows the construction of an interactive metabolic pathway map (p. 73). Ishizuka et al. shows the interactive map provides the advantage of presenting fundamental knowledge in biology and biochemistry (p. 73).

Nakao et al. in view of Ishizuka et al. do not show the data regarding human metabolism is exclusively used to create the interactive map.

Takai-Igarashi et al. shows a process of reconstructing pathways. Takai-Igarashi et al. shows that data is collected regarding human metabolism in a database, reading linked data regarding human metabolism exclusively used to create the interactive map (p. 130). Takai-Igarashi et al. shows biochemical units comprising chemical compounds reactions, metabolic steps, and enzymatic functions (p. 145). Takai-Igarashi et al. shows enzymatic functions comprise genes and proteins (p. 145). Takai-Igarashi et al. shows an annotation table with at least one field (p. 136). Takai-Igarashi et al. shows a field showing organ/tissue localization (p. 135 and 145). Takai-Igarashi et al. shows that in humans, metabolic pathways are more complex than other phyla such as bacteria

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due to the interconnections between pathways that are considered important for the evolution of elaborate mechanisms that enable individual cells to communicate with one another to coordinate behavior for the benefit of the whole organism (p. 130).

It would have been obvious to one of ordinary skill in the art at the time of invention to modify the method of reconstructing an organism's metabolism of Nakao et al. with the drug target identification of Karp et al. because Karp et al. shows that that integrated genome-metabolic pathways provide a framework for improved drug discovery. It would have been further obvious to modify the method of reconstructing metabolism with collected data of Nakao and the use of pathways to identify targets of Karp et al. with the DMD's of Kuffner et al. because Kuffner et al. shows DMD's allow the display of significant differences, to identify gaps in specific pathways and enable the interpretation of expression data by making predictions for proteins of unknown function and to propose the existence and/or absence of specific proteins or protein functions.

It would have been obvious to one of ordinary skill in the art at the time of invention to modify the reconstruction of a mammalian, or any organism's, metabolic pathway map of Nakao et al., in view of Karp et al., and in view of Kuffner et al. with the interactive metabolic pathway map of Ishizuka et al. because Ishizuka et al. shows the interactive map provides the advantage of presenting fundamental knowledge in biology and biochemistry. It would have been further obvious to one of ordinary skill in the art to further modify the method of metabolic reconstruction of Nakao et al., in view of Karp et al., in view of Kuffner et al., and in view of Ishizuka et al. by creating a map exclusively

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from human data as shown by Takai-Igarashi et al. because Takai-Igarashi et al. shows that in humans metabolic pathways are more complex than other phyla such as bacteria due to the interconnections between pathways which are considered important for the evolution of elaborate mechanisms that enable individual cells to communicate with one another to coordinate behavior for the benefit of the whole organism.

Response to Arguments

Applicant's arguments filed 08 October 2009 have been fully considered but they are not persuasive. Applicant argues Nakao et al., in view of Karp et al., in view of Kuffner et al. fails to show the limitations of the claims as instantly amended. The argument is not persuasive. The rejection has been amended to show that the limitations of the instantly amended claims are described by Takai-Igarashi et al. Takai-Igarashi et al. shows a system called Pathway Finding for the Cell Signaling Networks Database (PaF-CSNDB), is based on our database for cell signaling networks (CSNDB) in human cells (p. 130). Takai-Igarashi et al. explicitly demonstrates pathways can be drawn automatically and exclusively from collected, linked human data. With respect to applicants argument that one of the key differences between the claimed invention and the art is that the present invention reconstructs mammalian metabolism from scratch. This is not persuasive for at least two reasons. First, the claims do not recite a method of reconstructing mammalian metabolism from scratch. The claims are directed to reconstructing human metabolism from collected data regarding human metabolism. Second, the claim does not specify any particular data but rather recites the broad limitation of "data regarding human metabolism". Based on the guidance in the

specification, "data regarding human metabolism" is not limited to human data (c.f. specification p. 5). The rejection is maintained.

Claim 6, 14, and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nakao et al. as supported by the KEGG table of contents as of February 1999(online resource, [<http://web.archive.org/web/19990203053246/www.genome.ad.jp/kegg/kegg2.html>]), in view of Karp et al. and in view of Kuffner et al. (Bioinformatics, Vol. 16, No. 9, p 825-836, 2000) as applied to claims 1, 3-5, 7-10, 13, and 15-18 above, and further in view of Okubo et al. (Nature Genetics, Vol. 2, p. 173-179, November 1992).

Claims 6 and 14 are directed to data that is Expressed sequence tag (EST) data.

Nakao et al., in view of Karp et al., in view of Kuffner et al., in view of Ishizuka et al. and in view of Takai-Igarashi et al. as applied to claims 1 and 3, 5 above teach a method of metabolic reconstruction.

Nakao et al., in view of Karp et al., in view of Kuffner et al., in view of Ishizuka et al. and in view of Takai-Igarashi et al. as applied to claims 1, 3-5, 7-10, 13, and 15-18 above do not show EST data.

Okubo et al. shows expression data that comprises EST data can be used in mapping (p. 178, col. 1). Okubo shows the advantage of using expressed sequence tags results from a comparison of data from the same cells under different physiological conditions that will aid in the understanding of cell- and time-dependent control of gene

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expression (p. 176-177, col. 2). Okubo et al. shows that maps of expressed genes will help in the search for biologically and industrially interesting genes (p. 173, col. 1).

It would have been obvious to one of skill in the art at the time of invention to modify the method of metabolism reconstruction of Nakao et al., in view of Karp et al., in view of Kuffner et al., in view of Ishizuka et al. and in view of Takai-Igarashi et al. as applied to claims 1, 3-5, 7-10, 13, and 15-18 above with the incorporation of EST data of Okubo et al. because Okubo et al. shows that a map of expressed genes will facilitate the search for biologically and industrially interesting genes.

Response to Arguments

Applicant's arguments filed 09 October 2009 have been fully considered but they are not persuasive. Applicant argues that Okubo et al does not cure the deficiencies of Nakao et al., in view of Karp et al., in view of Kuffner et al. The argument is not persuasive for the reasons provided above. Nakao et al., in view of Karp et al., in view of Kuffner et al., in view of Ishizuka et al. and in view of Takai-Igarashi et al. shows the elements of the instantly claimed invention.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir.

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1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

This rejection is reiterated from the previous Office Action.

Claims 3, 7, and 8 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1 and 4 of copending Application No. 11/499, 437. Although the conflicting claims are not identical, they are not patentably distinct from each other because Both claim 3 of the instant application and claim 1 of Application No. 11/499, 437 are directed to the same use, namely to identify drug targets. Claim 1 of Application no. 11/499,437 is alternatively directed to identifying gene therapy targets. Both claim 3 of the instant application and claim 1 of Application No. 11/499, 437 perform the same steps and produce the same result. In addition, claims 7 and 8 of the instant application are directed to further limitation of the data specifically chemical compounds, reading on metabolite of as recited in claim 4 of Application No. 11/499, 437, and proteins, also as recited in claim 4 of Application No. 11/499, 437.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

The following double patenting rejection is maintained from a previous action and has been amended as necessitated by amendment.

Claims 1, 3, 5-10, 13-25 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 2-13 of copending Application No. 10/174, 762. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of both applications are drawn to the reconstruction of metabolic pathways of an organism. Both claimed inventions rely on the collection of data regarding an organism's metabolism; linking the data into metabolic pathways and identifying interconnections between metabolic pathways. The claimed inventions also have embodiments in which the data is heterogeneous, expressed sequence tag data, and directed to humans. The claimed inventions also recite embodiments comprising annotation tables directed to localization information.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to KARLHEINZ R. SKOWRONEK whose telephone number is (571)272-9047. The examiner can normally be reached on 8:00am-5:00pm Monday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marjorie Moran can be reached on (571) 272-0720. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/KARLHEINZ R SKOWRONEK/
Examiner, Art Unit 1631

21 January 2010